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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,864	10/13/2000	Jeffrey A. Ledbetter	034474.0003 UTLI	1294

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BUCHANAN INGERSOLL, P.C.
ONE OXFORD CENTRE, 301 GRANT STREET
20TH FLOOR
PITTSBURGH, PA 15219

EXAMINER

PARKIN, JEFFREY S

ART UNIT

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1648

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Please find below and/or attached an Office communication concerning this application or proceeding.

Serial No.: 09/687,864

Applicants: Ledbetter, J. A., and
M. Hayden-Ledbetter

Docket No.: 034474.0003

Filing Date: 10/13/00

Response to Election

Applicants are hereby advised that the communication filed on 21 August, 2003, is non-responsive to the prior Office action because it failed to properly elect an invention. Claims 1-14 were canceled in said communication and new claims 15-33 submitted. Applicants were advised in the last Office action to elect a **single antigenic domain** (i.e., one of HIV-1 gp160, bacterial antigen, tumor antigen, etc.) and a **single receptor binding domain** (i.e., one of CD154, single chain Fv specific for CD40, an Ig specific for CD40, etc.). Applicants were advised that this is not a species election, but rather a restriction requirement. Each of the identified combinations (i.e., HIV-1 gp160-CD154, HIV-1 gp160-single chain Fv specific for CD40, etc.) is directed toward a structurally and functionally distinct fusion protein. Separate searches will clearly be required for each fusion protein. Since the response appears to be *bona fide*, but through an apparent oversight or inadvertence failed to provide a complete response, applicant is required to complete the response within a **TIME LIMIT** of **one (1) month or thirty (30) days** from the mailing date of this letter, whichever is longer, within which to supply the correction in order to avoid abandonment. **EXTENSIONS OF THIS TIME LIMIT MAY BE GRANTED UNDER 37 C.F.R. § 1.136(a).**

Applicants have also amended the claim language and submitted new claims to include additional embodiments that are independent and distinct from the originally presented invention as set forth below.

35 U.S.C. § 121

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- a. Group I, claim(s) 15-22, 26, 27, 28, and 30, drawn to compositions comprising a **fusion protein** containing an **antigenic domain** linked to a **receptor binding domain** and expression vectors encoding said proteins, classified in class 435, subclass 69.7, class 424, subclasses 192.1, 208.1, 234.1, and 277.1, and class 530, subclass 350.
- b. Group II, claim(s) 15-21 and 23-33, drawn to nucleic acids encoding a **fusion protein** containing an **antigenic domain** linked to a **receptor binding domain** and expression vectors encoding said proteins, classified in class 536, subclass 23.72.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each identified group is directed toward structurally and functionally different compounds (i.e., protein, nucleic acids). Separate searches will also be required for each invention.

As previously set forth, applicants are advised that each combination of an antigenic domain (e.g., HIV-1 gp160, tumor antigen, bacterial antigen) and receptor binding domain (e.g., CD40-binding, CD154, single chain Fv, CD80-binding, CD86-binding, etc.) constitutes an independent and distinct invention.¹ Accordingly, a single antigenic domain (i.e., one of HIV-1 gp160, bacterial antigen, tumor antigen, etc.) and a single receptor binding domain (one of CD154, single chain Fv specific for CD40,

¹ Due to the inordinate number of inventions (e.g., HIV-1 gp160-CD154, HIV-1 gp160-single chain Fv, HIV-1 gp160-CD80-binding domain, HIV-1 gp160-CD86 binding domain, bacterial antigen-CD154, bacterial antigen-single chain Fv, bacterial antigen-CD80-binding domain, bacterial antigen-CD86 binding domain, tumor antigen-CD154, tumor antigen-single chain Fv, tumor antigen-CD80-binding domain, tumor antigen-CD86 binding domain, etc.) it was not feasible to set forth each one individually. However, as set forth in the restriction requirement, each combination of antigen and receptor binding domain constitutes an independent and distinct invention.

etc.) should be elected pursuant to 35 U.S.C. § 121. This is NOT a species election requirement. Each of the identified fusion proteins are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each fusion protein will have a substantially different structure and attendant biochemical and immunological properties. Moreover, separate searches will be required for each invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143). **Applicant is also advised that the claims should be amended to reflect the election, where necessary.**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(I).

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice

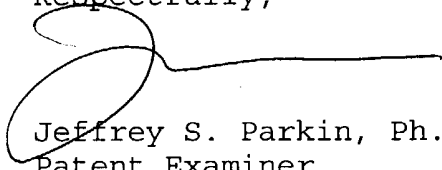
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mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Direct general inquiries to the Technology Center 1600 receptionist at (571) 272-1600.

Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

30 May, 2004